



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/840,143	05/06/2004	Jayant Ekanth Khanolkar	9626	7415
27752	7590	03/10/2009	EXAMINER	
THE PROCTER & GAMBLE COMPANY			PALENIK, JEFFREY T	
Global Legal Department - IP				
Sycamore Building - 4th Floor			ART UNIT	PAPER NUMBER
299 East Sixth Street			1615	
CINCINNATI, OH 45202				
			MAIL DATE	DELIVERY MODE
			03/10/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/840,143	KHANOLKAR ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Jeffrey T. Palenik	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 29 September 2008.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-4,6-12 and 14-17 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-4,6-12 and 14-17 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_.

**DETAILED ACTION**

Receipt is acknowledged of Applicants' Amendments and Remarks filed 29 September 2008. The Examiner acknowledges the following:

Claims 5 and 13 have been cancelled and the limitations amended into claims 1 and 11, respectively. Thus claims 1 and 11 are the only two claims which have been amended and are still under consideration.

No new claims have been added.

No matter has been added.

Thus, claims 1-4, 6-12 and 14-17 now represent all claims currently under consideration.

**INFORMATION DISCLOSURE STATEMENT**

No new Information Disclosure Statement (IDS) have been submitted for consideration.

**WITHDRAWN OBJECTIONS/REJECTIONS**

Rejection under 35 USC 102(b)

Applicants' amendments to the independent claims 1 and 11, as discussed above, render moot the rejection to claims 1, 2, 4, 7-11 and 15-17, under 35 USC 102(b) as being anticipated by Cuca et al. (USPN 5,002,777). Thus, said rejection has been **withdrawn**.

#### **MAINTAINED REJECTIONS**

The following rejection is maintained from the previous Office Correspondence dated 7 May 2008 since the art which was previously cited continues to read on the amended limitations.

#### **CLAIM REJECTIONS - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wen et al. (USPN 6,001,392).

The instant independent claims are drawn to a soft gel capsule composition and its preparation method. Dependent claims 3 and 12 further limit the active agent of the composition to specific categories of drugs such as antitussives and analgesics. Claims 5, 6, 13 and 14 further limit the stabilizing agent to a disodium salt of ethylene diamine tetraacetic acid (e.g. disodium edetate).

Wen et al. teaches in claim 1, a sustained release composition whose coated portion comprises 20-80% by weight of a suspended pharmaceutical active (e.g. a drug/resin complex). Said pharmaceutical may be an antitussive such as dextromethorphan (claims 4 and 5) or another type such as an analgesic, an anti-inflammatory, or an antipyretic drug (claim 7). Stabilizing agents (e.g. preservatives) such as methylparaben and propylparaben are taught in formulation at 0.08% and 0.05%, respectively (Examples). Other preservatives such as disodium EDTA are taught as being functionally equivalent to the formulation (col. 7, lines 60-65). Polyethylene glycol and water are also taught in the formulation (Examples). Methods of preparation are taught in Example 1 and preparation of the composition as encapsulated liquid suspensions is taught (col. 6, lines 38-44).

Wen does not specifically teach disodium EDTA, polyethylene glycol or water, within the respective ranges as claimed by Applicants'. Since the values of each parameter with respect to the claimed composition are adjustable, it follows that each is a result-effective parameter that a person having ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to be motivated to substitute in disodium EDTA as a functionally equivalent preservative to methyl- and/or propylparaben and still expect to successfully achieve the desired encapsulated pharmaceutically active suspension. It would have been equally customary for an artisan of ordinary skill to adjust the compositional percentages of all three components and in order achieve the desired encapsulated formulation. Thus, absent some demonstration of unexpected results from the claimed parameters,

optimization of any of these parameters would have been obvious at the time of Applicant's invention.

#### **RESPONSE TO ARGUMENTS**

Applicants' arguments with regard to the rejection of remaining claims 1-4, 6-12 and 14-17, under 35 USC 103(a) over Wen et al. have been fully considered but they are not persuasive.

Applicants allege that both PEG and EDTA are taught by Wen as having different uses/functions as opposed to those which are recited by the instant application. Applicants further allege that the skilled artisan would not have been motivated to optimize either the amounts of PEG or EDTA, particularly since 1.) a limited range of about 5% to about 20% is taught for PEG, and 2.) there is no express teaching of any amount of EDTA; all of the teachings are directed to using different amounts of the functionally equivalent paraben compounds.

In response to Applicants' remarks concerning the functionality of both PEG and EDTA, said remarks are unpersuasive in view of MPEP §§2111.01 (II) and 2141.03 (V), both of which state that "a compound and all its properties are inseparable". For example, whether PEG is used as a solvent or an humectant in the invention practiced by Wen is irrelevant. The fact still remains that Wen teaches using PEG in its practiced composition. Thus absent any evidence to the contrary, the presence of PEG in the art reads on its presence within the claimed composition.

Concerning the remarks regarding the optimization of the amounts of both PEG and EDTA which are taught by Wen, Applicants have provided no critical evidence to support their assertion that the skilled artisan would not have been motivated to add EDTA to the formulation in the amounts which are instantly claimed. Rather Applicants remark that EDTA is mentioned

only as an equivalent preservative to methyl- and ethylparaben, both of which are exemplified throughout Wen, whereas EDTA is not. The Examiner respectfully submits that since EDTA and the paraben compounds are expressly taught as functionally equivalent components employed within the practiced invention, follows that the skilled artisan would be motivated to substitute EDTA for either of the compounds. Furthermore, given that each of the Examples teach using both methylparaben and ethylparaben in such minute quantities (e.g. 0.08% and 0.05%, respectively), it follows that the ordinarily skilled artisan would have been motivated to routinely experiment with similarly small amounts of substituted EDTA.

For these reasons, Applicants' arguments are found unpersuasive. Said rejection is therefore maintained.

All claims under consideration remain rejected; no claims are allowed.

## CONCLUSION

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

#### **CORRESPONDENCE**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/  
Examiner, Art Unit 1615

/MP WOODWARD/  
Supervisory Patent Examiner, Art Unit 1615